

Executive Summary for Malathion ESA Assessment

This Biological Evaluation (BE) assesses whether the registered uses of malathion (PC code 057701), based on the U.S. Environmental Protection Agency's (EPA) proposed federal action, will result in a potential effect to an individual of an endangered and threatened (listed) species and/or its designated critical habitats. The evaluation also includes analysis of impacts to candidate species as well as species and critical habitat proposed for listing for conferencing purposes under section 7 of the Endangered Species Act (ESA). This evaluation, conducted as part of the registration review process (EPA's action under consultation), is based on interim scientific methods developed in response to recommendations of the National Research Council (NRC, 2013) and uses a three-step consultation process.

Step 1 consists of two parts: 1) establishing the action area for the proposed action, and 2) overlaying the listed, proposed, and candidate species (hereafter, "listed species" ranges and proposed and final critical habitat designations (hereafter, "critical habitat(s)" onto the action area (**Section 1.4.1**). This step identifies which species and critical habitats have the potential to be affected by the proposed action. A "no effect" determination is made for species and critical habitats whose ranges do not overlap with the action area and listed species that are presumed extinct as identified in the species reports. The categorization of "presumed extinct" are often difficult to ascertain and will be reviewed through outreach with FWS headquarters and field offices, as needed. Any listed species and/or critical habitat that warrants a "may affect" determination in Step 1 (*i.e.*, its range and/or critical habitat overlaps spatially with the action area and it is not presumed extinct) continues for further analysis in Step 2. Step 2 determines whether effects to individuals of listed species and/or Primary Constituent Elements (PCEs)/physical and biological features (PBFs) of critical habitat result in a "may affect, not likely to adversely affect (NLAA) determination, or a "may affect, likely to adversely affect" (LAA) determination. In Step 2, toxicity (indirect and direct effects data) and exposure information are analyzed using a weight-of-evidence (WoE) approach. These data are organized into lines of evidence that inform risk hypotheses and ultimately the effect determinations for listed species and their critical habitats. The NLAA determinations are submitted to the US Fish and Wildlife Service and the National Marine Fisheries Services (the Services) for concurrence, while the listed resources with a LAA determination are considered by the Services in their Biological Opinions (Step 3). This Biological Evaluation represents Steps 1 and 2 in the ESA pesticide consultation process for malathion.

General Information

Malathion is an organophosphate insecticide used on a wide variety of terrestrial food and feed crops, terrestrial non-food crops, aquatic food, non-agricultural indoor, outdoor sites, and for wide area public health uses. There is currently one active technical registrant for malathion and 96 active registrations (43 Section 3s, 53 Section 24c Special Local Needs, and no Section 18 Emergency Exemptions) which include formulated end-use products and technical grade malathion (see **APPENDIX 1-2**). Currently, there are 4 malathion products that are co-formulated with other active-ingredients. Malathion can be applied in a dust, liquid or encapsulated form. Aerial and ground application methods (including broadcast, fogger, and chemigation) are allowed (see **APPENDIX 1-3** for details).

Malathion will enter the environment via spray directly onto soil, foliage, or impervious surfaces. Spray drift and runoff are primary routes of offsite transport with volatilization and leaching occurring under certain conditions. Rainfall transports malathion off-field through runoff, soil erosion, and leaching. The primary route for malathion dissipation is microbial metabolism to malathion dicarboxylic and monocarboxylic acids (malathion DCA and malathion MCA, respectively). However, if malathion is in

contact with metabolically inactive surfaces such as dry soils or impervious surfaces common in non-agricultural settings, photo-oxidation to the degradate malaoxon can occur. Malaoxon dissipates and degrades similarly to malathion. Malathion DCA and MCA are not considered residues of toxicological concern (see **APPENDIX 1-9**).

Malathion is an organophosphate insecticide used to kill insects systemically and on contact. Organophosphate toxicity in animals is based on the inhibition of the enzyme acetylcholinesterase (AChE). Inhibition of AChE interferes with proper neurotransmission in cholinergic synapses and neuromuscular junctions which can lead to sublethal effects and mortality. The effects of malathion have been studied extensively in many taxa, particularly in fish and aquatic and terrestrial invertebrates (see **Chapter 2**). The BE considered more than 900 ecotoxicity studies for malathion (including (approximates) 225 fish and aquatic-phase amphibian studies, 260 aquatic invertebrate studies, 25 aquatic plant studies, 47 bird studies, 7 reptile and terrestrial-phase amphibian studies, 150 mammalian studies, 140 terrestrial invertebrate studies, and 49 terrestrial plant studies). Studies include acute and chronic laboratory studies with either technical or formulated malathion, and include both registrant-submitted and open literature studies (search of relevant open literature data conducted up through August 2013). Toxicity to taxa from exposure to other chemical stressors of concern (*i.e.*, malathion oxon, mixtures [*e.g.*, tank mixtures, formulated products, and environmental mixtures]) and non-chemical stressors (*e.g.*, temperature) are also considered.

Exposure Methods

Exposure values are based primarily on fate and transport model results. For aquatic exposures, the Pesticide in Water Calculator (PWC, v. 1.52, May 2016)[a new graphical user interface used to run Pesticide Root Zone Model (PRZM)/Variable Volume Water Body Model (VVWM)], AgDRIFT and AGricultural DISPersal (AGDISP) models are used to predict aquatic exposure in generic habitats, referred to as bins (see **Section 1.4.2.2.a.1.**). Aquatic exposure results for the bin(s) most appropriate for the species and/or critical habitat being assessed are used. For terrestrial exposures, existing models [*e.g.*, TerrPlant, AgDRIFT, AGDISP, earthworm fugacity model, Terrestrial Herpetofaunal Exposure Residue Program Simulation (T-HERPS), Terrestrial Residue Exposure model (T-REX) and portions of the Terrestrial Investigation Model (TIM)] were combined into a single tool that is referred to as the Terrestrial Effects Determination tool (TED)(see **Section 1.4.2.2.a.2.** and **ATTACHMENT 1-7**). A more detailed analysis using TIM and the Markov Chain Nest Productivity Model (MCnest) is also conducted for a subset of listed bird species. The models used in this BE can be found at [[HYPERLINK "https://www.epa.gov/endangered-species/provisional-models-endangered-species-pesticide-assessments"](https://www.epa.gov/endangered-species/provisional-models-endangered-species-pesticide-assessments)].

Overlap Analyses

The mosquito adulticide is presumed to overlap with all of the listed species ranges and critical habitats because it has no specific geographic footprint. Other use layers (as identified in **ATTACHMENTS 1-2** and **1-3**) that overlap with a large percentage of listed species ranges and critical habitats (*i.e.*, these use sites overlap with ~50 – 90% of the species and critical habitats, by number) include: developed land, open space developed, pasture, other grains, vegetables and ground fruit, other row crops, orchards and vineyards, wheat, and corn. The actual degree of overlap of specific uses with a particular species range varies widely and will be impacted by off-site transport distances (*e.g.*, spray drift and downstream transport).

Effects Determinations

To help determine the potential for risk, effects thresholds are established (see Interim agreement¹). For mortality to animals, the one-in-a-million chance of mortality [based either on the 5th percentile of the Species Sensitivity Distribution (SSD) or a surrogate LD₅₀, LC₅₀, or EC_x] is used to assess direct effects to a listed species (for details, see **ATTACHMENT 1-4**). For potential indirect effects based on prey lethality for those species without obligate relationships, the exposure that results in a 10% effect for the 5th percentile species on an SSD for the prey species or the 10% effect level for the most sensitive prey species tested (if not enough data are available for a SSD) is used. For sublethal effects, the direct effects threshold for animals and plants is the lowest available NOAEC/NOAEL or other scientifically defensible effect threshold (EC_x) that can be linked to survival or reproduction. For animals, the indirect effects threshold is the LOAEC/LOAEL for growth or reproduction for relevant taxa. For plants and indirect effects, the threshold is the lowest available LOAEC or EC₅₀ value (aquatic plants) and the lowest LOAEC or EC₂₅ value (terrestrial and wetland plants). These thresholds are used with other available data in a weight-of-evidence (WoE) approach which integrates the body of evidence that is available for making an effects determination. For the exposure assessment, the overlap of species range and action area, the relevance of predictive models to simulate EECs, the quality of fate data for exposure modeling and monitoring data that may be available are considered. For the effects analysis, the number of studies and/or species tested in the available toxicity data, taxonomic surrogacy, the magnitude and/or types of effects observed, and incident data are considered. An overall risk finding (high, medium, low) and a finding on the overall confidence (high, medium, low) in the available exposure and effects data is made for each line of evidence to inform the effect determinations for listed species and critical habitats (see **ATTACHMENT 1-9**).

Effects Determinations Summary

Because of the multitude of uses and use patterns for malathion (including the mosquito adulticide use), the action area for malathion covers the entire US, including its territories. Therefore, all of the listed species ranges and critical habitats overlap with the action area and the “no effect” determinations largely involve species that are believed to be extinct (or extirpated from specific geographic areas) in USFWS documents and referenced in EPA species reports, but have not yet been delisted.

For malathion, the results of the Step 1 (**‘No Effect’** (NE) or **‘May Affect’** determinations) and Step 2 (**‘Not Likely to Adversely Affect’** (NLAA) or **‘Likely to Adversely Affect’** (LAA) determinations) for species and designated critical habitats are presented in **Tables 1** and **2**, respectively. For species/critical habitats with a NE determination in Step 1, no additional analyses are conducted (they do not proceed to Step 2). For malathion, all of the uses and use patterns modeled, result in threshold exceedances for most taxa. For species/critical habitats with NLAA determinations, they will be sent to the Services for concurrence. For species/critical habitats with a LAA determination, additional analyses will be conducted (*i.e.*, they proceed to Step 3).

¹ Interim approaches and agreement: [[HYPERLINK "https://www.epa.gov/endangered-species/interim-approaches-pesticide-endangered-species-act-assessments-based-nas-report"](https://www.epa.gov/endangered-species/interim-approaches-pesticide-endangered-species-act-assessments-based-nas-report)]

TABLE 1. Summary of Species Effects Determinations for Malathion (Counts by Taxon).

TAXON	STEP 1 EFFECTS DETERMINATION		STEP 2 EFFECTS DETERMINATIONS		Totals
	NO EFFECT	MAY AFFECT	NOT LIKELY TO ADVERSELY AFFECT	LIKELY TO ADVERSELY AFFECT	
Amphibians	0	40	1	39	40
Aquatic Invertebrates	0	220	1	219	220
Birds	5	103	12	91	108
Fish	0	193	5	188	193
Mammals	2	107	20	87	109
Plants	0	961	2	959	961
Reptiles	0	48	0	48	48
Terrestrial Invertebrates	9	147	0	147	156
Total	16	1819	41	1778	1835
Percent of Total Number of Species (%)	1	99	2	97	

TABLE 2. Summary of Critical Habitat Effects Determinations for Malathion (Counts by Taxon).

DESIGNATED CRITICAL HABITAT TAXON	STEP 1 EFFECTS DETERMINATION		STEP 2 EFFECTS DETERMINATIONS		Totals
	NO EFFECT	MAY AFFECT	NOT LIKELY TO ADVERSELY AFFECT	LIKELY TO ADVERSELY AFFECT	
Amphibians	0	25	0	25	25
Aquatic Invertebrates	0	75	0	75	75
Birds	0	31	0	31	31
Fish	0	106	0	106	106
Mammals	0	32	5	27	32
Plants	0	462	3	459	462
Reptiles	0	17	0	17	17
Terrestrial Invertebrates	0	46	2	44	46
Total	0	794	10	784	794
Percent of Total Number of Critical Habitats (%)	0	100	2	98	